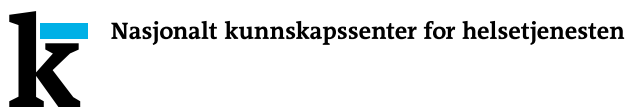


The effect of early intervention programmes for families at risk, on the psychiatric outcomes of small children aged 3 and under

Rapport fra Kunnskapssenteret Nr 4-2006

Systematisk kunnskapsoppsummering



Background: Norwegian authorities wish to approach small children in families at risk more systematically and proactively. This summary of available research will be a part of a larger report that evaluates one of the initiatives in the Government's Action plan for child and adolescent mental health. **Main question:** What is the effect of early intervention on the mental health of small children (aged three and under) in families at risk? **Metode:** We searched for systematic reviews and health technology assessments of randomised controlled trials of early interventions evaluated and recommended internationally. We looked for reviews that attempted to assess the effect on mental health in small children aged three years or less in families at risk. **Results:** We included five systematic reviews, but none of them evaluated mental health outcomes in small children. Based on these systematic reviews, we identified 11 relevant randomised trials, most of which reported cognitive or behavioural outcomes. Population, intervention and outcomes varied a lot between these studies. **Conclusion:** This summary shows that there is currently little systematic research

(fortsetter på baksiden)

Nasjonalt kunnskapssenter for helsetjenesten
Postboks 7004, St. Olavs plass
N-0130 Oslo
(+47) 23 25 50 00
www.kunnskapssenteret.no
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(fortsettelsen fra forsiden) available on the effect of early interventions on the mental health of small children aged three years or less. Thus it is not possible to conclude what effect early interventions may have on the mental health of small children. We found some evidence that developmental programs aimed at teenage mothers and their children can benefit the children's cognitive development. The research also indicates that educational programs for parents can improve behaviour for children with behavioural problems, but this does not include autistic children.

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Institusjon	Nasjonalt kunnskapssenter for helsetjenesten
Ansvarlig	John-Arne Røttingen, direktør Signe Flottorp, forskningsleder
Forfatter	Meetali Kakad
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Foreword

In summer 2006, the Norwegian Knowledge Centre for the Health Services (Kunnskapssenteret) was asked to assist in a project commissioned by the Regional Centre for Child and Adolescent Psychiatry (R.BUP), in Oslo. The main focus of the project was to evaluate the effect of early intervention on the psychiatric outcomes of young children and infants (aged 0 to 3 years) from so-called high risk families, when compared to other interventions, standard care, or no intervention at all.

The project mandate was as follows:

- **Map out evaluated an internationally recommended interventions for small children in families at risk***

This report is an overview of systematic reviews. A systematic review is an overview of primary studies, produced according to an explicit and reproducible methodology where the aims, objectives, materials and methods have been explicitly stated(1).

We have searched for systematic reviews that are primarily based on randomised controlled trials. Due to time constraints and the broad nature of the original research question, we have used strict inclusion criteria to limit the scope of the project. This potentially has an impact of the generalisability of the results reported here

This document has been produced by Meetalı Kakad, a senior advisor at the Norwegian Knowledge Centre for the Health Services.

Abstract

Bakgrunn

Nasjonal satsing på sped- og småbarn

Målet med å oppsummere erfaringer og tilgjengelig forskning er å stimulere til større satsing på sped- og småbarn i risikofamilier i hele landet. Sosial- og helsedirektoratet har allerede etablert et Nasjonalt kompetansenettverk for sped- og småbarns psykiske helse. (Se www.r-bup.no)

Denne oppsummeringen av tilgjengelig forskning vil inngå i en større rapport fra R.BUP Øst og Sør om ”Systematiske tiltak for sped- og småbarn i risikofamilier”, jamfør Tiltak 42 i Regjeringens handlingsplan for barn og unges psykiske helse⁽²⁾.

Problemstilling

Hvordan påvirker tidlige hjelpetiltak den psykiske helsen til sped- og småbarn (0 til 3 år) i risikofamilier? Kunnskapscenteret fikk i oppgave å utrede dette spørsmålet i samarbeid med Regionsenteret for barn og unges psykiske helse, helseregion Øst og Sør (R.BUP).

Mandat

Å oppsummere den forskningen som finnes om evaluerte og internasjonalt anbefalte tidlige tiltak for psykisk helse hos små barn i risikofamilier.

Hva er tidlige intervensjoner?

Med tidlige tiltak mener vi ulike tilnærminger og programmer som skal fremme barns psykiske, sosiale og kognitive utvikling.

Hva er risikofamilier?

R.BUP og sin fagfellegruppe definerte risikofamilier som familier hvor

- foreldrene ikke er i stand til å beskytte barna sine mot virkningene av sosiale problemer
- foreldrene ikke er i stand til å beskytte barna sine mot virkningene av sine egne psykiske problemer, eller barnas psykiske problemer, eller
- barnas egne behov er så kompliserte at de hindrer foreldrenes evne til empati eller til å kommunisere godt med barnet

Metoder

Vi søkte etter systematiske oversikter og HTA-rapporter over randomiserte kontrollerte studier frem til juni 2006.. Vi gjennomgikk den vitenskapelige

litteraturen som finnes om hvilken effekt tidlige intervensjoner har på sped- og små barns psykiske helse, sammenlignet med fravær fra intervensjoner, andre intervensjoner eller rutine tjenester. Oversiktene som oppfylte våre inklusjonskriterier ble kritisk vurdert. Deretter oppsummerte vi resultatene fra de oversiktene som var av god eller moderat metodisk kvalitet. Resultatene er presentert i tekst og tabell. Oversiktene ble gruppert etter hvilken risiko barna var utsatt for: sosioøkonomisk (miljø-), biologisk eller fysisk, psykisk og utviklingsmessig sykdom/lidelse. Noen av oversiktene inkluderte primærstudier som ikke var aktuelle for vår problemstilling. Vi oppsummerte derfor bare resultatene fra 11 primærstudier.

Resultater

Fem oversikter ble inkludert etter kritisk vurdering. Alle oversiktene var av god kvalitet. Ingen av oversiktene inkluderte psykiske utfallsmål hos sped- og småbarn. Ut fra oversiktene identifiserte vi 11 randomiserte studier var relevante for vår problemstilling. De fleste studiene rapporterte bare kognitive eller atferdsrelaterte utfall. Populasjon, intervensjon og utfallsmål varierte mye blant de studiene vi inkluderte.

Konklusjoner

Vår oppsummering viser at det finnes få systematiske oversikter som handler om effekten av tidlig intervensjon på psykisk helse hos sped- og småbarn. Det er derfor ikke mulig å si noe sikkert om effekten av tidlig intervensjon i forhold til småbarns psykiske helse. De fleste oversiktene vi har sett på, målte effekten av tidlig intervensjon på atferd, kognitive utfall eller andre relaterte utfall.

Ut fra de systematiske oversiktene fant vi 11 relevante primærstudier som oppfylte våre inklusjonskriterier. Overførbarheten mellom studiene og forskjellige studiepopulasjonene ble begrenset på grunn av stor heterogenitet i typene intervensjoner og populasjoner som ble inkludert. Dessuten varierte kvaliteten av de inkluderte primærstudiene.

Vi fant få, men noen, studier som viste at utviklingsstøttende programmer rettet mot tenåringsmødre og deres barn har en positiv effekt på barn – i forhold til kognitiv utvikling. Noen av studiene vi har inkludert viste at det var mulig at pedagogiske programmer for foreldre kunne forbedre atferd i barn med atferdslidelse, men ikke for barn med autisme.

Det er et stort behov for flere gode systematiske oversikter og primærstudier som fokuserer på effekten av tidlig intervensjon på psykisk helse hos sped- og små barn.

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Introduction

The Southern and Eastern Regional centre for Child and Adolescent psychiatry (R.BUP Øst og Sør) received a request from the Directorate for Health and Social Affairs (SHDir) to evaluate initiative 42 in the Government's Action Plan for Child and Adolescent Mental Health(2). As part of this Action Plan, the SHDir, in partnership with the child welfare authorities, would evaluate experience obtained from systematic work directed towards "high risk" families with small children, carried out both in Norway and internationally. The ultimate aim of this evaluation would be to inform the development of recommendations in this area, to be implemented on a national basis.

The background for this project has been described in the Government's Strategic Plan. Of particular relevance is a chapter entitled "Children and young people's encounters with society" (2) where the following programme goals are stated:

- A society characterised by tolerance
- A health promoting and protecting society
- Strengthening an individual's own resources – thus reducing unnecessary medicalisation of a problem

Under the aim "a health promoting and protecting society" it is stated that:

"Det er godt dokumentert at tidlig hjelp er god hjelp. Når barn har det dårlig og er i ferd med å utvikle psykiske, atferdsmessige eller kroppslige symptomer, er det viktig at voksne tar ansvar for å bidra eller skaffe nødvendig støtte og hjelp. Det er mulig å identifisere mange risikoutsatte småbarn. Likevel klarer vi bare å finne fram til tredjeparten av 2-3 åringene som vil ha utviklet alvorlige vansker som 4 – 5 åringene. For å nå fram til tiltak til en enda større andel av de barna som vil komme til å utvikle vansker senere i barnealder, er det nødvendig både å sette inn forebyggende tiltak rettet mot alle barn, unge og familier i risikozonen og mot barn og unge som allerede har utviklet psykiske problemer og lidelser"*

* "It is well documented that early help is effective help...When children are in difficult situations and at potential risk of developing psychiatric, behavioural or physical symptoms, it is important that adults take responsibility to provide or obtain support and assistance. It is possible to identify these vulnerable young children, but in spite of this we only manage to do it in only a third of 2 to 3 year olds who go on to develop serious difficulties as 4 or 5 year olds. In order to successfully intervene in a greater proportion of these cases, it is essential that preventative measures are in place. These programmes must be directed towards both at-risk children and young people, and those that already have developed mental health related problems or disorders".

The task that Kunnskapssenteret has been asked to undertake, is one of several that R.BUP is responsible for. These include:

- Defining the concept of “families at risk”
- Identify possible risk factors influencing the development of child and adolescent mental health problems.
- Provide an overview of systematic work with families defined as high risk, especially with regards to child welfare or health services provided at a municipal and national level, together with the Child, youth and family directorate.
- **Working in partnership with Kunnskapssenteret, to assess interventions evaluated and recommended internationally, for use with young children in high risk families.**

The principal objective of these efforts is to bring together the available scientific literature on those interventions with a documented effect on the mental health of young children. These findings will be published in a more extensive report by R.BUP on the use of early intervention in young children and infants.

Why use early intervention?

There have been several reasons proposed as to why early intervention may be important:

- The physical and mental health of women during pregnancy has an impact on the health of the newborn child and early bonding(3)
- The emergence of problems early in life has a strong correlation with difficulties at a later age(4)
- Early experiences are important for brain development
- Children that have a known disorder, require special attention to ensure optimal development(5)

R.BUP has been particularly interested in approaches and methods that can:

- Reduce the occurrence of development disorders/delays (cognitive, motor, behavioural and social) in children from high risk families

- Promote positive development for children from high risk families who already have developed one or other form of development disorder
- Target, in particular, high risk families and those who might have a need for help both before and after birth

Concepts used in this report

R.BUP was asked to define the principal concepts central to our research question:

Families at risk

These are families where parents are not able to protect their children from the effects of either:

- social problems affecting the family
- psychiatric or psychological difficulties – affecting either parents or the children themselves
- or where the child's own needs are so complicated that they impair the parents' ability to empathise or communicate successfully with the child.

Early intervention

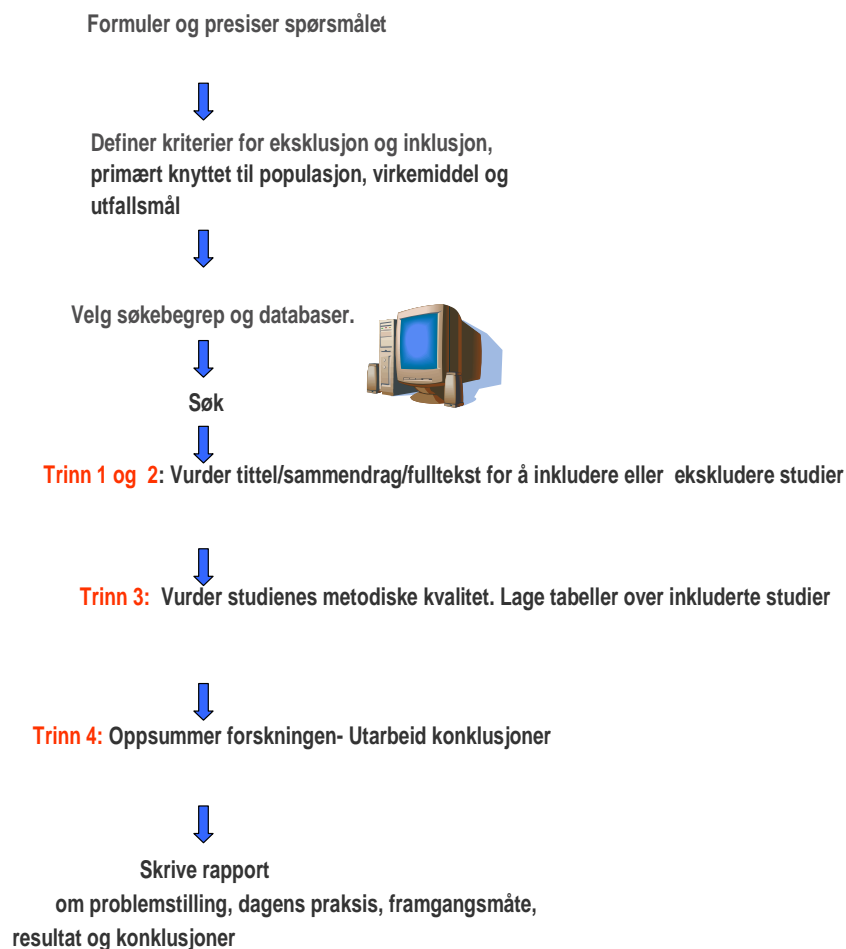
The use of early intervention for mental health in at risk families with young children principally refers to a broad selection of approaches and programmes which are designed to protect child development

In this instance early intervention does not refer solely to secondary prevention but includes primary and targeted primary interventions also.

Methods

This report is a systematic and critical exploration of the available scientific literature. Only those reviews satisfying the inclusion criteria pertaining to this overview of overviews have been included. The process of systematically procuring and critically evaluating the literature was carried out according to methods stated in the Kunnskapscenteret's handbook, as set out in the figure below (6).

Fremgangsmåte for kunnskapsoppsummeringen



Mandate

Map out programmes/interventions targeting small children in high risk families. Relevant interventions must have been evaluated and recommended internationally.

Inclusion criteria

- Study design:** Systematic reviews and Health Technology Assessments of randomised controlled trials
- Language:** English and Scandinavian
- Population:** Infants and small children (0-3 years), parents and pregnant women in high risk families
- Intervention:** Early intervention:
- Primary prevention (universal)
 - Targeted primary prevention
 - Secondary prevention /treatment
- Outcomes:** Only child-related outcomes were considered:
- Mental Health
 - o Diagnosis of psychiatric disorder
 - o Admission to psychiatric unit
 - o Suicide attempt
 - o etc
 - Behavioural
 - Antisocial behaviour – substance misuse, violence
 - Cognitive

Exclusion criteria

Due to the limited time and human resource available, the additional criteria stated below were applied when determining which reviews should be excluded in the final evaluation.

Ease of data extraction:

- If it was not possible to rapidly extract relevant data or ascertain the ages of children involved in individual primary studies, a review was excluded. This applied, in particular, to reviews lacking tables containing descriptions of the studies included.

Population:

- If the search strategy had not incorporated a means of explicitly detecting studies with high risk study populations (as defined by us), the review was excluded.

Outcome:

- A review was excluded if the outcomes of interest did not include at least one psychiatric or behavioural (including antisocial behaviour^{*}) outcome. This means that reviews focusing entirely on neglect/abuse or cognitive outcomes went out.

Age:

- A review was excluded if the majority of individual studies included, were carried out on children above 3 years. Where a study was merely stated “preschool children” or “kindergarten children”, it was also excluded. If the mean of the target age range was above 3, the study was also discounted - this practice also applies to the creation of the evidence tables (Tables p34)

Norwegian practice

A national competence network exists for infants and small children’s mental health. The objective for this network is to contribute to knowledge development, improving competency and strengthening of those interventions that promote the mental health of young children. The target measure of success for the network is that more young children and their families get effective help as early as possible. A conference in Oslo in April 2006, “Early interventions for Infants and Small Children in Families at risk” drew together experts in the area of early intervention from around the world.

Literature search

The research librarian, Karianne Thune-Hammerstrøm, carried out a systematic search as according to Kunnskapssenteret’s handbook (6) and in consultation with the project-leader Meetalı Kakad and R.BUP. We searched in the following databases (See appendix 1 for the search strategy).

- The Cochrane Library
- EMBASE
- PsycINFO
- MedLine
- Campbell database

In addition to the general search of the Cochrane Library, we carried out a hand search of the reviews published by six Cochrane Groups with a potentially relevant focus:

^{*} These include rates teenage pregnancy, substance misuse and delinquency occurring in the target population of children.

- Drug and Alcohol
- Depression, Anxiety and Neurosis
- Schizophrenia
- Developmental, Psychosocial and Learning Problems
- Neonatal
- Pregnancy and Childbirth

The Campbell Library was also searched for relevant reviews. The Campbell collaboration prepares, maintains and disseminates systematic reviews of studies of interventions concerning education, crime & justice and social welfare.

The results of the searches in the individual databases are shown in the table below:

Results of the search

Database	References obtained
The Cochrane Library (including hand searching of reviews published by relevant Cochrane groups*)	136
MEDLINE	254
PsychINFO	640
EMBASE	416
Campbell Library (hand search)	9

Evaluation of article abstracts and in full text

Level 1: The title and abstracts of a total of 1454 articles were screened for relevance (see inclusion criteria) by MK. The majority of these articles did not fulfill the inclusion criteria for this report and some were duplicates.

Level 2: 109 articles were considered of sufficient relevance to be evaluated in full text form. We managed to obtain 104 of these, within the timeframe allowed for the project. Two further articles were added - one of which was a

* Drug and Alcohol, Depression, Anxiety and Neurosis, Schizophrenia, Developmental, Psychosocial and Learning Problems, Neonatal and Pregnancy and Childbirth Cochrane groups.

Cochrane review published in July 2006 after our initial search and the other was a systematic review mentioned in another overview of overviews captured by our initial search(7;8). Many of the articles found could not be defined as systematic reviews according to our standards(1); they were either primary studies or descriptive literature reviews, often carried out without an explicit or systematic search strategy. These studies and reviews were excluded, along with other overviews of overviews – though these were screened for relevant systematic reviews that could potentially be included.

Critical appraisal of methodological quality and description of reviews in tables

Five systematic reviews were included(9-13). The information from the Cochrane review by Coren et al, was supplemented with information from another article by the same authors, based on the same dataset(10). The newer article also included additional information on studies other than randomised controlled trials (RCTs).

These five reviews constitute the knowledge base for this report. A critical appraisal of these articles was carried out by MK using the checklist found in appendix 2. The findings of the reviews have been described in tabular form (tables, p 34-44) and also in the text.

Given the heterogeneous populations included in the definition of “families at risk” and the broad range of interventions sought after, we felt that some form of grouping of similar categories was appropriate. In this situation – given the relatively few reviews included in final report – it may appear unnecessary, as there are only one or two reviews in each group. However, the range of populations, interventions and outcomes even in this small group of five reviews, further highlights the problems with trying to extrapolate conclusions further than the boundaries of each individual review.

Several potential groupings were considered:

- by risk group, i.e. children at risk from :
 - o Socioeconomic risk (so-called environmental risk)
 - o Biological risk/existing behaviour problems but otherwise normal
 - o Children with physical or cognitive delays and disabilities and children with chronic medical illness

- by intervention type:
 - o Primary prevention
 - o Targeted primary prevention

- Secondary prevention

The potential difficulty in grouping reviews by type of intervention is that they often focus on several types of intervention. R.BUP was keen to include all types of intervention, though it is possible to argue that early intervention should only refer to secondary forms of prevention, i.e. target those children who already have a diagnosis of behavioural or psychiatric problems.

Intervention type could also be deconstructed further:

- By target group:
 - intervention focussed directly at parents
 - intervention focussed at children
 - intervention focussed at families

This is further complicated by the fact that even where the intervention was focussed at parents, for example training in behavioural techniques, the subsequent recipients of that intervention were children. In some studies, the target group of the intervention was not always clearly stated.

- By intervention type:
 - Behavioural interventions
 - Cognitive interventions
 - Home visiting etc.
- By outcomes for the children concerned:
 - Psychiatric outcomes
 - Behavioural/Antisocial behaviour
 - Cognitive

In this report the reviews were grouped according to risk partly as a pragmatic solution, and partly what was felt to be the most clinically relevant. An alternative may have been to use the target group of the intervention, which were the parents for all but one of the studies included.

Consolidating the knowledge base and deriving conclusions

The results from the reviews included were summarised in a descriptive manner. Due to the necessarily stringent search criteria and limited time available, it should be acknowledged that results may have limited generalisability. Possible alternative approaches and potential future research projects are suggested in the discussion chapter.

Results

Five systematic reviews form the foundations of this report. They have been grouped according to the risk, as previously described in the Methods chapter (p14). They were all considered to be of good methodological quality.

Socioeconomic / environmental risk

Coren 2001 (Cochrane), Coren 2003(9;10)

Coren et al published a Cochrane review in 2001 with a follow up article published elsewhere in 2003(9;10). The Cochrane review was based entirely on four randomised controlled trials, though only two of these had measured outcomes considered relevant to this project. The later article included these four randomised controlled trials and ten other non-randomised or uncontrolled studies. The methodology and search strategy used in both articles was otherwise virtually identical and of good quality.

Both reviews evaluated the effectiveness of individual and group-based parenting programmes in improving psychosocial outcomes for teenage parents and their children. The two studies considered relevant for this report were both of relatively poor methodological quality. The main focus of the intervention in both the studies considered suitable for inclusion here was teenage mothers^(14;15). The sample sizes for both studies were relatively small – especially in Koniak-Griffin’s study with only 31 volunteer mothers, with no sample size calculation carried out in either case. Therefore the power of the study and its ability to detect an effect was not known. Losses to follow-up were not documented by Koniack-Griffin but were 33% in the study by Truss, who provided additional information on the reasons given for leaving the program.

The interventions used in each paper were quite different though were both focussed at parents; one study assessed a one-to-one parenting programme⁽¹⁵⁾ and the other a group parenting programme with a postal educational component, designed to enhance mother-infant interaction⁽¹⁴⁾. The one to one programme was geared towards improving maternal behaviour, whilst the group intervention was targeted towards enhancing infant cognitive development and preventing or reducing developmental delay.

Neither of these studies measured mental health outcomes. Koniak-Griffin assessed mother-infant interaction and used the Responsiveness to Parents subscale, to quantify how much the infant responded positively to the parent.

The results showed a strongly positive but not statistically significant effect, that favoured the intervention group, with a standardised mean difference (fixed) of -0.71 (95% CI -1.44, 0.02).

The outcomes reported from Truss' study were all cognitive in nature and based on the emergence of language – both receptive and expressive and the development of language. All the results presented showed non-significant effects of varying magnitude, favouring infants in the intervention group. Overall both studies presented here reported positive outcomes favouring the intervention group, but that did not reach statistical significance.

There were no additional randomised controlled trials included in the article published in 2003, though there was one other randomised study considered relevant for inclusion here⁽¹⁶⁾. As Badger randomised individuals to two intervention groups, it was not immediately obvious as to why Coren et al chose not to include this study as an RCT. The authors of the study were contacted for further clarification. They reported that whilst the Badger study had used randomisation, it had not fulfilled the inclusion criteria for the review: The review only included studies where there had been randomisation to a no-treatment or wait-list control group. Studies utilising an alternative treatment group as the control group were excluded. The authors of the Coren review stated that they could have listed Badger separately as a randomised study without a no-treatment or wait-list control group.

The aim of the study carried out by Badger was to evaluate the effect of group-based programmes that reinforce the maternal role, on preventing deficits and developmental delay in infants. The authors compared two interventions: the first being a weekly group based parenting programme aimed at teenage mothers aged 16 years or older and the second being a monthly home-visiting programme. The focus of the study was on fostering better mother-infant interaction and infant development.

Badger used both the Uzgiris-Hunt Ordinal Scales of Infant Development and the Bayley Scales of Infant Development to assess the effectiveness of both interventions in promoting infant development^{*†}. Participants were stratified according to risk. Coren's article only reports that the study showed a statistically significant difference in favour of the group based programme, in promoting development ($p < 0.01$). This effect was more pronounced in high risk mothers but no further information was provided by the study.

* The Uzgiri-Hunt measurement tool includes various measures of infant development

† The Bayley Scales of Infant Development (BSID) measure infant development scales from a mental (cognitive), motor and behavioural perspective of infants from one to 42 months of age. The scales have been extensively used worldwide to assess infant development.

Using the BSID, the only significant difference reported was that infants of high risk mothers in the group programme had better mean mental scores than the equivalent group receiving home visits. The same group also had better mean motor scores than infants of both high and low risk mothers in the home visit group ($p < 0.05$ for both).

Doggett 2005(13)

This Cochrane review looked at the effect of pre- and postnatal home visits for women with existing drug and alcohol problems. Whilst the main focus appeared to be on drug and alcohol use by these women, outcomes measured included all important parent and infant related benefits and harms. The authors chose to carry out extensive subgroup analysis, which is not fully reported here.

The review found six randomised controlled trials comparing home visits with no home visits, for mothers with a drug or alcohol problem. Four of those studies were considered relevant for inclusion here(17-25).

The four studies included had significant methodological limitations, with generally poor reporting of randomisation methods, allocation concealment and blinding. With the exception of Schuler, which had substantial losses to follow up nonetheless, the three other studies had relatively small sample sizes, with no accompanying calculations of statistical power. Black, Butz and Schuler reported blinding to treatment allocation in only a few of their outcome measures: BSID, Child Behaviour Checklist (CBCL), videotaped observations of mother-child interaction, respectively.

All four of these studies enrolled women on the basis of self-reported drug use. Black, Butz and Schuler enrolled women of largely African-American origin. There was substantial variation in terms of the types of home visitors and the nature of the interventions used. Only Black used both pre- and postnatal visits, whilst the others only provided visits after the birth.

Home visiting can generally be considered an intervention at the level of the family, though it often incorporates a specific more targeted component. Three studies incorporated some form of developmental intervention, with the same theoretical base, as part of the home visiting intervention. Interestingly, the effects on longer term development were inconsistent, with Black reporting no difference in the Bayley Scales Mental Development Index (MDI) or the psychomotor development index (PDI) at 18 months but Schuler reporting

significant psychomotor improvement in the intervention group. Longer term cognitive outcomes and school achievements were not reported.

Grant found no reduction in the incidence of cognitive delay at 3 years using the MDI, Relative Risk (RR) 1.36, (95% CI 0.41 to 4.45), but a borderline statistically significant increase in the incidence of psychomotor delay using the PDI, RR 3.26 (95% CI 1.00 to 10.59). Meta-analysis of Black, Grant and Schuler found no significant difference in cognitive development or psychomotor development.

Neither Coran nor Doggett reported on any direct psychiatric outcomes or longer term measures assessing education attainment, teenage pregnancy, unemployment or criminal behaviour.

Biological risk/behavioural disorders

Dimond 1999(12)

This review focussed on the medium to long term effectiveness of parent education programmes for childhood behaviour problems. Methodologically the review was of good to moderate quality and well documented, though non-randomised controlled studies were also included.

Nineteen studies were included in the final report, of which three randomised controlled trials were considered relevant to this report (26-28).

The studies were rated using a quality code out of five (5 being the highest possible score): Tucker and Gross scored three out of five(28), with both Webster-Stratton & Hammond and Van den Boon scoring four(26;27). This suggests that they were of good to moderate methodological quality.

There is only limited information on methodological flaws available in the review. Tucker and Gross was rated as lower in quality, in part due to the small sample size of 23. Blinded outcome assessment was reported for the Van den Boon study, with independent assessment of some outcomes also carried out in Webster, Stratton & Hammond (though blinding was not mentioned).

Most of the interventions differed superficially in terms of the number of sessions and teaching methodologies etc but were of a similar format in that they were session-based and used a standardised parent education package. As with the other systematic reviews discussed here, there was a wide range of outcomes reported. Given this heterogeneity, only well known and previously validated outcome measures were reported by the reviewers.

Whilst the review included other studies that attempted to assess long term outcomes and antisocial behaviour outcomes, none were suitable for inclusion here. The review did not specifically attempt to evaluate any effect on psychiatric outcomes for the children concerned.

Only two of the three studies discussed here showed statistically significant positive effects on child behaviour in the intervention group. Webster Stratton and Hammond reported statistically significant positive effects ($p < 0.001$) for all the outcome measures presented in Dimond's review, including the Eyberg Child Behaviour Inventory (ECBI) and the CBCL (see table II, p40)*.

The main focus of Van den Boom's intervention was improving maternal sensitivity, with attachment being the only child related outcome. A positive improvement in attachment was seen in the intervention group with an effect size of 0.23[†]. The p value for the effect was reported inconsistently between tables, but was reported as non-significant in the text.

Tucker & Gross reported a mixture of significant and non-significant results. Using the ECBI, they reported a positive but non significant change in behavioural improvements in the intervention group. The ECBI i (identification of problematic behaviours) had an effect size of 0.44, ($p < 0.05$), whilst the ECBI f (frequency of occurrence) had a non significant effect size of 0.17

Existing disease, developmental disorder or disability

Diggle 2002(11)

This Cochrane review only included two small studies ((29;30)). The review itself looked at the extent to which parent mediated early intervention is effective in treating children aged 1-7 years with Autistic Spectrum Disorder. Jocelyn's study was excluded as the mean of the age range was above 3 years of age(30).

Smith carried out a study of 28 children aged between 18 and 24 months and their parents(29). The study was of good quality with both randomisation and

* The ECBI is designed to assess parental report of conduct behavioral problems in children and adolescents ages 2-16 and measures the number of difficult behavior problems and the frequency with which they occur(12). The CBCL consists of 118 items listed on a 0-2 scale that constitute a multiple problem behaviour score. It is possible to get a total behaviour score or a social score.

[†] Given the general heterogeneity of the studies, a formal meta-analysis was not considered appropriate. In order to comment on the overall direction and magnitude of effect, where the appropriate data was available, a standardised mean effect size was calculated using the formula $(\text{Mean experimental group} - \text{mean control group}) / \text{Standard deviation control group}$ or $(\text{Mean t1} - \text{Mean t2}) / \text{Standard deviation t1..}$

allocation concealment methods documented, and with blinded outcome assessment carried out. There were no losses to follow up reported.

The study aimed to compare intensive treatment (a child orientated intervention) to parent training. Intensive treatment based on the Lovaas(31) treatment manual was given to 15 children, who received 30 hours intervention per week for 2 to 3 years. Parent training was given to the parents of thirteen children. These parents were taught the Lovaas methods in two weekly sessions continuing for a period of 3 to 9 months. The children also received 10-15 hours special education during the parent training period.

This review did not explicitly set out to assess the impact on child mental health outcomes, nor was there an attempt to review the impact on other longer term outcomes. The main focus was on cognitive and behavioural outcomes.

In general the results favour the intensive treatment group: this group had statistically significant results in relation to higher IQ, with a mean difference (MD) of 16.82 (95% CI 0.58 to 33.06, $p=0.04$)^{*}. Statistical significance was also attained for the Merrill Palmer Scale of Mental Tests with a MD of 15.16 (95% CI 0.14 to 30.18, $p=0.04$).

Those measures that relied on reports by teachers and parents including the Vineland Adaptive Behaviour Scales[†] and CBCL did not reach statistical significance, nor were they of clinical significance.

^{*} as measured by the Stanford Binet Intelligence Scale, Thorndike and Bayley MDI scale.

[†] The Vineland Adaptive Behavior Scales (VABS) were designed to assess handicapped and non-handicapped persons from birth to adulthood in their personal and social functioning

Discussion

It is difficult to make statements about the strength of the entire knowledge base in this area for several reasons: One of these reasons is that we have deliberately been very strict in our inclusion criteria, given the limited time available. Only those reviews which explicitly mentioned they searched for high risk populations and included at least one psychiatric or behaviour outcome were included, thus substantially reducing the number of eligible articles. A number of reviews included primary studies carried out on high risk populations, but had not initially set out to capture these. With greater resource and time, it is possible that some of these primary studies could have been discussed further in this report.

On the basis of the systematic work carried out to inform this report, it is not really possible to answer the question “does early intervention have a positive effect on the psychiatric outcomes of small children and infants (aged 0 to 3 years) living in families at risk”. There is a paucity of information regards these outcomes in children of all ages, but this is especially true for very young children. There is, however, more information available on other potentially relevant outcomes, such as those assessing behavioural and cognitive function.

The evidence base

Whilst the five reviews included here were of good methodological quality, the quality of the primary studies they included was highly variable(9-13). None of the reviews reported on any direct mental health outcomes, focussing more on those related to behaviour and cognitive function. This may potentially be a result of the relative difficulties in diagnosing mental illness in this age group but also the difficulty in obtaining longer term outcomes where there were losses to follow up.

The systematic reviews included here contained relatively few primary studies – with even fewer of these suitable for inclusion here, primarily on the grounds of age of the children involved(14-28). Several of the reviews discussed in this report included studies of children both above and below 3 years of age.

This report, however, focuses on those primary studies that fulfilled our inclusion criteria; it is therefore possible to draw discrepant conclusions when considering the individual results of these few studies presented here, out of the context of systematic reviews they were taken from. The conclusion of the

review are based on all the included studies and thus potentially on children older than 3 years.

Environmental risk

Whilst Coren and Doggett both looked at outcomes for children with some kind of environmental risk, the risk populations and interventions were sufficiently different to make generalisations both difficult and inadvisable(9;10;13). Coren assessed both individual and group parenting programmes for teenage parents, whilst Doggett focussed on pre- and postnatal home-visiting for women with drug and alcohol problems.

The Cochrane review published by Coren in 2001, included four RCTs - with their later publication from 2003, including a further ten non-randomised studies. Only two of the randomised trials and one controlled study were suitable for inclusion here (14-16).

The two randomised trials included both produced sizeable but nonsignificant results favouring the intervention group. The study by Badger, which randomised individuals to one of two interventions, reported that infant development outcomes were better for those high risk infants whose mothers received the group intervention.

Whilst Koniak Griffin utilised a group based parent orientated intervention aimed at fostering maternal-infant interaction, Truss used an individual based parenting programme more focussed on child development. Badger targeted both interaction and child development and compared group based parenting as in Koniak-Griffin, with a home visiting programme. From these three studies alone, it is not possible to say whether interventions targeting teenage mothers improve behavioural or cognitive outcomes, with only Badger reporting significant outcomes^{*}. Given the magnitude of the effect size shown in the other two studies, and the small sample sizes, it reasonable to consider the studies as possibly underpowered. The heterogeneity between the studies makes it unfeasible to generalise further.

Whilst the two systematic reviews differ slightly in the certainty of their overall conclusions; the Cochrane review tentatively suggests there *might* be a positive effect of parenting programmes on child outcomes, whilst the later review (including a majority of non-randomised studies) suggests parenting programmes *can* positively affect psychosocial and developmental outcomes for

^{*} The information report in Coren 2003 was very limited and with no effect sizes shown and no confidence intervals.

teenage mothers and their children. It should be noted that both studies refer to the variable methodological quality of the included studies.

Doggett's review used multiple subgroup analysis in an attempt to combat the heterogeneity of the 6 included primary studies(13). This rendered the results of this review rather difficult to interpret. The overall conclusions of the review are influenced by the preponderance of small, low quality trials. They state that there is insufficient evidence to recommend the routine use of home visits in order to improve outcomes for women with drug or alcohol problems and their children. In terms of child related outcomes, only Schuler reported a significant effect on psychosocial development in infants receiving the intervention(18-23). All other studies measuring child development outcomes reported no significant difference between intervention and control groups.

Four studies from Doggett were suitable for inclusion in our overview of overviews(17-25). All four studies had methodological limitations. Three of these studies incorporated development interventions as part of the home visits (Black, Butz, Schuler) using a common educational basis(17;25). As stated above, only Schuler reported any significant findings. It should be noted that all these studies had substantial losses to follow up, meaning that the results should be viewed with caution. Grant who used only paraprofessional home visitors and did not have a development component, showed no significant improvement in the intervention group. Longer term social or educational outcomes were not reported in any of these studies.

Given the substantial variation between these, Coren and Doggett's reviews and the lack of information on psychiatric outcomes, it is not possible to generalise further with regards to "early interventions" and their impact on the mental health of young children. All three reviews express concerns over the methodological quality of the included trials and the generalisability of the results – with small samples size, heterogeneity of intervention and outcome measures being the predominant concern. Based on the seven primary studies discussed here, there is only very weak evidence to suggest that that parenting programmes or home visiting improve either psychosocial or development outcomes for young children and infants from families at risk.

Biological risk / behavioural disorders

Dimond's review from 1999 included 19 studies, of which 15 provided information on the effect of parent education on child behaviour. Three of these studies were suitable for inclusion here. Overall the review was of moderate quality with a focus on medium to longer term measures of effectiveness. Whilst the authors carried out quality ratings based on valid criteria, it was not

always straightforward to extract the information for individual studies from the text.

The overall conclusion of the review was there were statistically significant improvements in the intervention group for child behaviour, at 1 year and possibly beyond. There were no measurements of psychiatric outcomes and studies assessing longer term outcomes, including antisocial behaviour did not meet our inclusion criteria.

The authors commented that the results were generally “more significantly positive” where group parenting education was the main intervention, rather than individually orientated. This must be interpreted with caution as the review itself did not set out to compare different interventions. The reporting of the results in the review was slightly confusing and multiple outcomes were reported across the studies, with few of the same outcomes being reported across several studies. The majority of results reported were pre- and post-test measures for the intervention group with an effect size reported alongside a p value.

Two of the three studies eligible for inclusion here (26;28) had significant effects on child behaviour at 1 year follow up, for children aged 3 and under. Whilst WSH reported a large and significant improvement as measured by ECBI, Tucker and Gross showed a positive but nonsignificant result, possibly due to the small sample size. There was significant heterogeneity between the interventions used by the three studies, though the review claimed they were all based on standardised education packages.

Overall there is limited evidence to suggest that that parent education might improve behaviour in small children with existing behaviour problems. However, this is based on a limited number of studies, with variable methodological quality, some with small sample sizes^{*}. It is not possible to comment on which programmes should be favoured over others, but there was a suggestion that group based programmes might have a greater effect. Further research is required to explicitly compare intervention types and their relative effectiveness.

Existing chronic disease, disability, developmental disorder or delay

Diggle’s review focussed on parent mediated early intervention for young children (1-7 years) with Autistic Spectrum Disorder. This was a Cochrane

^{*} It was difficult to assess loss to follow up explicitly from the information in the text of the review, though the authors had considered this in their construction of the “quality code”

review of good methodological quality, however it only included two studies, only one of which met the inclusion criteria for this report(29). As with the previous reviews only behavioural and cognitive outcomes were reported, though the authors searched for all objective child related outcome measures.

As the authors rightly point out, the results of this review must be viewed with caution: This is in part due to the very small number of included studies, which themselves had small sample sizes but also as these two studies differed in context, approach, duration and intensity of intervention. It was felt that design flaws in the studies meant that it was not possible to assess the extent to which the intervention was effective.

Smith found significant effects on two ability measures (IQ) in the intervention group. It is likely; however, that the tool used to measure IQ was not consistent for the pre- and post-intervention measurements as there was an interval of 5 years between them. This casts doubt over the magnitude of the real effect.

Based on the evidence available it is not possible to draw any conclusions as to whether active early involvement of parents improves outcomes for young children with autism. It is highly unlikely that any conclusions can be generalised to children with chronic illness or developmental delay.

Methodological issues

The research question central to this project was sufficiently complex to raise several methodological issues: These tended to focus upon the lack of similarities between studies, specifically in terms of population, intervention and outcomes.

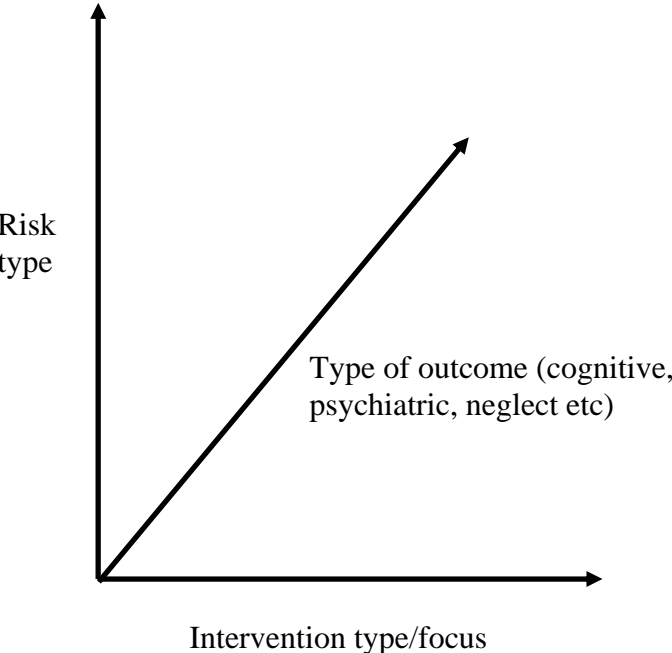
Defining “early intervention” and “families at risk” was also a considerable challenge as no formally agreed definitions existed. Moreover, translating a narrative definition into clearly defined search terms required considerable effort and interpretation; this was achieved by consensus between R.BUP and Kunnskapssenteret.

An additional problem arose in terms of choosing which outcome measure to use. Given that mental health outcomes were not included in those overviews reviewed here, only cognitive and behavioural outcomes were presented. It remains a matter for discussion whether these outcomes are appropriate proxies for the psychiatric welfare of young children at risk. Cognitive and behavioural outcomes are likely to be potentially relevant performance indicators for certain intervention programmes.

The heterogeneity of our target population, “families at risk” means that attempting to generalise across risk populations, on the basis of diverse results across diverse trial populations, is likely to be inappropriate. For this reason meta-analysis was only carried out in a limited number of reviews, who dealt with substantial inter-study variations by carrying out extensive subgroup analysis.

In order to present the data, it was possible to group reviews in many ways – both according to risk population, intervention type/target group, outcome measurements, or combinations of these. These multiple possibilities can be thought of in the form of a 3 dimensional matrix, in this example, which potentially provides a means of structuring future research questions and reviews in this field.

The reviews in this report are few in number and thus only cover a very small proportion of the “matrix”.



An example of a matrix for framing research questions

Overviews of overviews are potentially limited when assessing complex interventions in complex populations because of inter-study and inter-review variation. They are often highly dependent on the quality of reporting within the systematic reviews. It is often a problem to fully appreciate the quality and finer details of included studies without going back to the primary studies themselves.

Unfortunately it was not possible to review individual primary studies in this instance, due to limited time available.

Conclusion

A sense of optimism has followed early intervention and its potential effect across different populations of “high risk” children. This is not necessarily justified when one reviews the literature systematically, according to the criteria used in this report. Early intervention research has moved away from the tendency to generalise positive effects in one group, across all risk populations – and this is substantiated by our work.

Our research question focussed on a small population of very young children; finding literature specifically on this age-group has proved difficult – in part because of the availability of relevant studies including children from 0 to 3 years, but also because we excluded studies with a very wide age range. With more time and the possibility to go back to the primary studies, it might have been possible to extend the knowledge base beyond that which is reported here. It is uncertain, however, how much this would have altered the findings of the report.

We found no reviews that reported mental health outcomes in this age group. Most studies focussed on behavioural and cognitive improvements. Early behaviour problems have been implicated in poorer mental health and behavioural outcomes, as have poor cognitive outcomes and developmental delay (32)

It has not been possible to combine all the sub-populations included in the “families at risk”-definition given the substantial differences between them. We have not attempted to generalise conclusions from one risk group* across to the other two. Similarly within each risk group, it may be difficult to generalise further than the population within the study. This is also a function of the small sample sizes, high losses to follow up and context/country specific nature of some of the populations and interventions.

There was very weak evidence to suggest that parenting programmes in teenage mothers had a positive effect on child related outcomes. Only one study, which was not described as an RCT reported a significant effect on development outcomes(16) The two RCTs had clinically rather than statistically significant effects on interaction and language related outcomes. Similarly there was

* Environmental, biological and existing disease, disability or delay

insufficient evidence to suggest that home visits in women with drug and alcohol problems had an impact on child developmental outcomes.

From the reviews and studies evaluated in this report, there is some evidence to suggest that parent education programmes improve behavioural outcomes in young children with existing behaviour problems. The length of time that this effect endures is less certain, though it would appear to hold for a minimum of a year.

For young children with autistic spectrum disorder, there was insufficient evidence to suggest that behavioural or cognitive function improved with parent-mediated early intervention.

Future work in this area

We have been made aware of a very recently published report, by the Social Care Institute for Excellence that is potentially of relevance. This document is a systematic map of the literature on parental mental health problems and the effects on the family. Systematic maps aim to describe the existing literature in a broad topic area and can be analysed in depth or more superficially as appropriate to individual projects. The report does not, however, attempt to make a quality assessment of the literature and is thus not a systematic review(33).

If one considers the use of overviews of overviews to evaluate this type of research question, an alternative approach to that used in this report would be to undertake a *series* of overviews of overviews. Each individual overview could focus on only one or two of the “dimensions” previously mentioned – for example a specific risk population and intervention type. This in itself could help to reduce some of the problems surrounding heterogeneity. Whilst reducing the scope of a project could potentially be seen as reducing its generalisability, in this instance, however, it is likely to make the results more meaningful. It is almost impossible to conceive a single early intervention program that would aim to target successfully these very diverse populations of young children, all considered at risk.

A prioritisation exercise, such as some kind of needs assessment, might assist in determining which of these reviews should be done first. Understanding the size of each type of risk population in Norway, and how many children are potentially at risk in each group, would be very useful.

Perhaps more importantly, is the continuing production of systematic reviews and primary studies of high quality, with similarly focussed research questions. The Campbell Collaboration has registered several protocols for reviews that could be of considerable relevance to this area and are worthy of follow up. High quality randomised controlled trials assessing relevant outcomes in young children using consistent measures are required. A particular focus on obtaining valid psychiatric and longer term outcomes is also vital.

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Tables

Table I-III Description of appropriate* primary studies included in Coren, Diggle, Doggett and Dimond

Intervention = All types of early intervention aimed at young children, parents and pregnant women in high risk families
Control= No intervention

*** only studies which included children within the target age range (0-3 years) or where the mean of the age range was less than 3 and had measured relevant outcomes were included**

Socioeconomic / environmental risk

Table I. Included primary studies in Coren and Doggett

Publication	Koniak-Griffin 1992 (Coren)	Truss 1977 (Coren)
Method	<p>Study design: Randomised controlled trial with <u>pre and post measures</u></p> <p>Methodological quality:</p> <ul style="list-style-type: none"> - Small sample size, with no power calculation carried out to determine whether it was adequate. Potential confounders were not discussed. - Blinding not possible in this situation and as no independent measures were used to assess outcomes, blinding was not required for outcome assessment,. - There was no documentation of loss to follow up or drop out rate and subsequently no mention of intention to treat analysis. 	<p>Study design: Randomised controlled trial with <u>pre and post measures</u>.</p> <p>Methodological quality:</p> <ul style="list-style-type: none"> - Relatively small sample size, with no power calculation carried out to determine whether it was adequate. Potential confounders were not discussed. - Blinding not possible in this situation and as no independent measures were used to assess outcomes, blinding was not required for outcome assessment,. - Loss to follow up documented but intention to treat analysis was not carried out, leading to possible overestimation of effect. However information was provided as to why parents did not continue and on certain demographic characteristic
Selection	<p>31 volunteer adolescent mothers < 20 years (mean age 17) with healthy infants recruited from a residential maternity home – n=15 in intervention group</p> <p>Control group: 16 in the control group</p>	<p>127 pregnant or parenting adolescents whose babes would be aged < 6 months at the start of the programme were recruited from outpatient clinic with a programme for teenage parents. All these individuals were teenage parents. n= 83 in the intervention group</p> <p>Control group: n=12. "Others" (unclear as to what this means) n=32. In the Cochrane</p>

Publication	Koniak-Griffin 1992 (Coren)	Truss 1977 (Coren)
	Country: USA	review the control group is stated as including 37 individuals, though only reports n=12 in the metaanalyses. Country : USA
Intervention	One- to-one parenting programme. Structured tasks used which were recorded on videotape, with feedback provided by a nursing professional. 2x video sessions Control group: Placebo control group (further clarification not given)	Group based parenting programme with mailing of booklets for 48 months (according to Cochrane review). Group based parenting programme - 3 hourly sessions over 12 weeks according to 2003 paper. Control: No clarification given as to intervention/placebo received
Outcome measurements	Child outcomes – responsiveness to parents, mother infant interactions	Cognitive development and language
Results	Responsiveness to parent: SMD -0.71 (95% CI -1.44 to 0.02) p=0.06 Mother-infant interaction: SMD -0.79 (95% CI -1.53 to -0.06)	Receptive language (Bzoch League scale): SMD -0.52 (95% CI -1.13 to 0.09), p=0.09 Emergent Language (Bzoch League scale): SMD -0.24 (95% CI -0.84 to 0.37), p=0.4 Emergent Language (Utah test): SMD -0.24 (95% CI -0.91 to 0.50) NB. WMD figures reported in Cochrane review: WMD -5.73 (95% CI -19.67 to 8.21) p=0.4
Comments	Small study, poor methods and documentation No mention of loss to follow up Limited generalisability	No allocation concealment specified Limited generalisability

Publication	Badger (1981)	
Method	Study design: Uncontrolled study with random assignment to one of two intervention groups (not described as an RCT in Coren 2003). Methodological quality: No control	

Publication	Badger (1981)	
Selection	Volunteer teenage mothers of infants recruited postnatally from a paediatric medical centre. Age \leq 16 years. Group based intervention n=24, Home visiting intervention n=24. Control: None. Country: USA	
Intervention	Not clear Group based parenting programme provided on a weekly basis, duration unknown Other intervention/ ? control in this instance– "home visiting" – number of visits or objective not specified	
Outcome measurements	Infant development	
Results	Not adequately reported in the systematic review Infant development significantly better in intervention group, $p < 0.01$ Mental development significantly better in intervention group, $p = 0.01$ Motor development significantly better in intervention group, $p < 0.01$	
Comments	Difficult to comment on methodological quality or success of interventions based on the information provided in the review.	

Publication	Black 1994	Butz, 1998
Method	Study design: Randomised controlled trial. Methodological quality good: <ul style="list-style-type: none"> - Method of randomisation not reported - Allocation concealment unclear - Blinding to intervention not possible 	Study design: Randomised controlled trial. Methodological quality: <ul style="list-style-type: none"> - Method of randomisation reported - computerisation - Allocation concealment carried out (envelopes used) - Blinding to intervention not possible

	<ul style="list-style-type: none"> - Blinded outcome assessment for Bayley Scales - Loss to follow up reported (17/60 – 11/31 treatment group, 6/29 control group) - ITT analysis used 	<ul style="list-style-type: none"> - Blinded outcome assessment for Child Behaviour checklist - Loss to follow up reported (87/204 lost to 36 month follow up – with 104/204 (52%) mother-infant pairs with incomplete data at follow up. 100 mother infant pairs available for all outcomes. Losses: 59/108 treatment group, 58/96 control group) - ITT analysis used
Selection	<p>Primarily single, african-american, low income, inner city , multiparous polydrug users, with incomplete schooling</p> <p>Age of women not reported. Maternal cocaine or heoin use inpregnancy obtained from questionnaire. Enrolled prenatally</p> <p>Control: Recruited from same source</p> <p>Country: USA</p>	<p>Delivery at one of two urban hospitals, maternal age 19-40 years. Use of maternal heroin or cocaine in pregancy (self reported or positive maternal/infant toxicology screen)</p> <p>Exclusion criteria included: adolescent and older mothers, infants < 35/40, mothers with major psychiatric diagnosis</p> <p>Control: Recruited from same source</p> <p>Country: USA</p>
Intervention	<p>Treatment group n=31: Two parttime experienced community health nurses provided 1 hour home visits pre and postpartum, biweekly extending to 18 months, with 2 visits prior to the birth. Formed alliance, addressed personal, family and environmental needs. Helped to facilitation interaction between parent and child. Provided information and advocacy.</p> <p>Used Carolina preschool Curriculum and Hawaii Early learning program</p> <p>Control group n=29: Received no home visits</p> <p>Co-interventions: Both intervention and control group attended primary health care multidiciplinary clinic dedicated to treating infants born either to substance abusing mothers and/or mothers with HIV infection. Nine clinic visits were scheduled up to 18 months of age (compensation</p>	<p>Treatment group n=59: 16 community paediatric nurse home visits from birth to 18 months. Emotional support. Helped to facilitation interaction between parent and child. Infant Health monitoring. Parent education, parental skills training.</p> <p>Used Carolina preschool Curriculum and Hawaii Early learning program</p> <p>Control group n=58: Received no home visits. Standard care (not described) with outpatient follow up.</p> <p>Co-interventions: None reported</p>

	and transport costs covered	
Relevant outcome measurements	Secondary outcomes: Child development at 6, 12 and 18 months (Bayley Scales of Infant Development)	Primary outcomes: Child Behavior checklist at 36 months
Results	Multiple subgroup analysis thus difficult to report all results here. Refer to Cochrane review Narratively reported that no difference in the Bayley Mental Development index or psychomotor index (PDI) at 18 months	Multiple subgroup analysis thus difficult to report all results here. Refer to Cochrane review Reported in the text Reduction in behaviour problems of borderline statistical significance: RR 0.46, 95% CI 0.21 to 1.01; RD -0.17, 95% CI -0.33 to -0.01 No significant difference in Child Behaviour Checklist total score at 18 months: WMD -3.10, 95% CI -7.26 to 1.06
Comments	Predominantly post partum visits in drug using women	Large losses to follow up

Publication	Grant, 1996	Schuler 2000 (this was based on published data only from six studies cited by the Cochrane review(18-23))
Method	Study design: Randomised controlled trial. Methodological quality good: <ul style="list-style-type: none"> - Method of randomisation not reported - Allocation concealment unclear - Blinding to intervention not possible - Blinded outcome assessment not reported - Loss to follow up reported (18/66 (27%) – 12/35 treatment group, 6/31 control group) - ITT analysis used 	Study design: Randomised controlled trial. Methodological quality: <ul style="list-style-type: none"> - Method of randomisation not reported - Allocation concealment unclear - Blinding to intervention not possible - Blinded outcome assessment - Loss to follow up reported 258 enrolled, 227 randomised at 2 weeks, 53/227 lost after 2 week visit, 174 (775) seen at 18 months but outcomes reported for 131 (58%). Losses for Bayley Scales at 18 months: 60/114 treatment group; 59/113 control group - ITT analysis used
Selection	Singleton birth,. Not engaged successfully with community services – minimal or no prenatal care.	Teaching hospital, largely African-American women with positive urine toxicology at birth or history of recent drug use.

	<p>Age of women not reported. selfreported heavy drug and/or alcohol use in pregnancy, hospital referred first day postpartum. Recruited within one month of delivery</p> <p>Control: Recruited from same source</p> <p>Country: USA</p>	<p>Enrolled postpartum</p> <p>Exclusions: Infants discharged into care, infants with congenital or serious developmental problems requiring intervention</p> <p>Control: Not specified</p> <p>Country: USA</p>
Intervention	<p>Home visit group n=35: The Seattle birth to 3 years programme – a 3 year homevisiting advocacy programme by paraprofessional advocates with many similar life experiences.</p> <p>Weekly home visits for 6 weeks, then twice monthly or more to 3 years.</p> <p>Linked clients with appropriate services</p> <p><u>No specific developmental intervention</u> but developmental assessment performed in intervention group at 4 months, 2 and 3 years</p> <p>Formed alliance, addressed personal, family and environmental needs. Helped to facilitation interaction between parent and child. Provided information and advocacy.</p> <p>Control group n=31: Received no home visits – access to community social and health services. Children evaluated at 3 years only</p> <p>Co-interventions: Both intervention and control group attended primary health care multidisciplinary clinic dedicated to treating infants born either to substance abusing mothers and/or mothers with HIV infection. Nine clinic visits were scheduled up to 18 months of age (compensation and transport costs covered</p>	<p>Treatment group n=114: Infant Health and Development Program comprising of a home-based intervention in first year, child attendance at a child-development centre and parent group meetings from the second year.</p> <p>Weekly home visits from birth to 6 months, biweekly to 18 months by lay African American women.</p> <p>Goal of homevisits to increase maternal empowerment and improve mother's ability to identify and manage problems using existing services and supports.</p> <p>Child component included Hawaii Early learning program</p> <p>Control group n=113: Short monthly home-tracking visits by a lay worker.</p> <p>Co-interventions: All mothers given information on drug treatment programs but participation not mandatory. Compensation and transport costs covered.</p>
Relevant outcome	<p>Secondary outcomes: Child development at 6, 12 and 18 months</p>	<p>Primary outcomes: Bayley Scales of infant developments at 18 months</p>

measurements	(Bayley Scales of Infant Development)	
Results	<p>Multiple subgroup analysis thus difficult to report all results here. Refer to Cochrane review</p> <p>Using paraprofessional home visitors and provided no specific developmental intervention, Grant failed to demonstrate any improvement in development outcomes no difference in the Bayley Mental Development index or psychomotor index (PDI) at 18 months</p> <p>Bayley MDI: No significant difference in incidence of cognitive delay at three years RR 1.36, 95% CI 0.41 to 4.45)</p> <p>Bayley PDI: An increase in incidence of psychomotor delay using of borderline significance RR 3.26, 95% CI 1.00 to 10.59; RD 0.27, 95% CI 0.03 to 0.51.</p>	<p>Multiple subgroup analysis thus difficult to report all results here. Refer to Cochrane review</p> <p>Reported in the text:</p> <p>Significant improvements in Bayley PDI for infants receiving intervention</p> <p>From a post hoc subgroup analysis, it was reported that the greatest effect of home visiting on development was seen in infants of mothers with no ongoing drug use</p>
Comments	Substantial loss to follow up	Large losses to follow up

Biological risk / behavioural disorders

Table II. Included primary studies Dimond (studies where the age range of the child population was defined only as "preschool" or "kindergarten", were excluded)

Publication	Tucker & Gross, 1998	Webster Stratton & Hammond, 1997
Method	<p>Study design: Randomised controlled trial.</p> <p>Methodological quality:</p> <ul style="list-style-type: none"> - Regarded as a moderate quality study according to scoring criteria with a score of 3. - No control group at long term follow up - No further details in text re randomisation and allocation concealment - Most outcomes recorded by the parent 	<p>Study design: Randomised controlled trial.</p> <p>Methodological quality:</p> <ul style="list-style-type: none"> - Regarded as a moderate quality study according to scoring criteria with a score of 4. - No control group at long term follow up - No further details in text re randomisation and allocation concealment

Publication	Tucker & Gross, 1998	Webster Stratton & Hammond, 1997
Selection	46 21-36 month old infants displaying negative behaviour Follow up at 1 year Country: ?	97 18-24 month olds with conduct problems Follow up at 1 year Country: ?
Intervention	Behavioural parent training Control group – not described ? nothing received	4 equal groups: - Parent training group (PT) - Child training group (CT) - Combined group (PT+CT) Control group – not described ? nothing received
Outcome measurements	Eyberg Child behaviour Inventory (ECBI) Child Behaviour checklist (CBC) Daily Parent record (PDR)	Eyberg Child behaviour Inventory (ECBI) Child Behaviour checklist (CBC) Daily Parent record (PDR)
Results	ECBI (l) (mother reported): Measure at T1(T1) = 108.83, Measure at T2(T2)= 101.92, Effect size (ES) =0.44, p<0.05 ECBI (f) (mother reported): T1 = 3.33, T2 = 2.58 , ES = 0.17 , not significant	ECBI (Mother): Measure at T1(T1) = 154.05, Measure at T2(T2)= 119.28, Effect size (ES) =1.96, p<0.001 ECBI (Father): T1 = 148, T2 = 108.31 , ES = 2.36 , p<0.001 CBCL (Mother): T1 = 67, T2 = 55.08 , ES = 0.77, p<0.001 CBCL (Father): T1 = 62.88, T2 = 53.5, ES = 1.1, p<0.001 PDR (-): T1 =10.67, T2 = 3.88, ES = 1.9 , p<0.001 PDR (+): T1 = 13.24, T2 = 4.4 , ES = 1.5, p<0.001
Comments	No parent assessment Lower quality study	No control group at long term follow up Both parents and independent observations made

Publication	Van den boom, 1995
Method	<p>Study design: Randomised controlled trial.</p> <p>Methodological quality:</p> <ul style="list-style-type: none"> - Regarded as a good quality study according to scoring criteria with a score of 4. - Not possible to assess randomisation method from information in the text or allocation concealment (though the reviewer did score for this) - Blinded outcome assessment
Selection	<p>82 irritable infants (as assessed by behaviour score) from low income</p> <p>Follow up at 3.5 year</p> <p>Country: Holland</p>
Intervention	<p>Home based skills training</p> <p>Control group – not described</p>
Outcome measurements	Dyadic parent child interaction (DPICS - attachment status)
Results	<p>DPICS (positive): Control = 0.06 Intervention = 0.24, ES = 0.23, not significant</p> <p>DPICS (negative): Control = 0.06 Intervention = 0.02, ES = 0.03, not significant</p>
Comments	Outcomes independently assessed with blindly

Developmental delays and disability, chronic illness

Table III. Included primary studies in Diggle

Publication	Smith 2000a
Method	<p>Study design: Randomised controlled trial.</p> <p>Methodological quality:</p> <ul style="list-style-type: none"> - Method of randomisation reported - random number table to carry out random matched pair allocation based on diagnosis and IQ - Allocation concealment stated as adequate - Assessments made by professionals blind to participants treatment. - No study drop outs reported - ITT analysis used
Selection	<p>Referrals to UCLA young autism project between 1989 and 1992. 28 children and their parents participated.</p> <p>Children aged between 18 and 24 months, within an hours drive of the centre, IQ 35-75 points, no major medical comorbidities</p> <p>Control: Not specified</p> <p>Follow up: 4 years and 10 months (mean)</p> <p>Country: USA</p>
Intervention	<p>Intensive treatment n=15: Based on Lovaas' treatment manual. Children received 30 hours intervention per week for 2 to 3 years. Treatment based, at least for the first 18 months, on discrete trial procedures, after this attended school with an aid, or special education classes</p> <p>Parent training (n=13) Parents were taught the treatment method (Lovaas). Given 2 sessions a week (5 hrs) for 3-9 months. Also received a 3-monthly consultation with the lead author. Children spend 10-15 hours in special education classes for the duration parent</p>

Publication	Smith 2000a
	training.
Outcome measurements	Behavioural: CBCL Cognitive: IQ
Results	Parent training vs Intensive treatment Overall intensive treatment group favoured: IQ – MD 16.82 (95% CI 0.58 to 33.06), p=0.04 Merrill-Palmer scale of Mental tests: MD 15.16 (95% CI 0.14 to 30.18), p=0.04 Vineland Adaptive Behaviour Scales and CBCL showed no statistical significance between groups
Comments	Limited sample size with no sample size calculation carried out Wide confidence intervals for significant results - ?clinically important

Appendix 1: Search strategy

Medline

1. exp Vulnerable Populations/
2. exp Risk Factors/
3. exp Risk Assessment/
4. (risk\$ or vulnerable\$).mp.
5. or/1-4

6. exp Mental Disorders/
7. exp Substance-Related Disorders/
8. exp Minority Groups/
9. exp Pregnancy in Adolescence/
10. exp Parent-Child Relations/
11. exp Learning Disorders/
12. exp "Child of Impaired Parents"/
13. exp Foster Home Care/
14. exp Social Problems/
15. exp Stress, Psychological/
16. exp Disabled Persons/
17. exp Mental Retardation/
18. exp Infant, Premature/ or exp Premature Birth/ or exp Infant, Premature, Diseases/
19. exp Child Development/
20. exp mental disorders diagnosed in childhood/
21. or/6-20

22. (parent\$ or famil\$ or mother\$ or father\$ or pregnan\$).mp

23. exp Child Development/
24. exp mental disorders diagnosed in childhood/
25. 23 or 24

26. (baby or babies or toddler\$).mp.
27. exp child, preschool/ or exp infant/
28. child\$.mp
29. or/26-28

30. (interven\$ or prevent\$ or program\$ or treatment\$ or effect\$ or therap\$ or outcome\$ or result\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]

31. 5 or 21
32. 31 and 22 and 29 and 30

Embase

1. exp Vulnerable Population/
2. exp Risk Factor/
3. exp Risk Assessment/
4. (risk\$ or vulnerable\$).mp.
5. or/1-4

6. exp Mental Disease/
7. exp social problem/
8. exp high risk population/
9. exp minority group/
10. exp Adolescent Pregnancy/
11. exp Child Parent Relation/
12. exp Learning Disorder/
13. exp Foster Care/
14. exp Prematurity/
15. exp Disability/
16. exp Mental Deficiency/
17. exp child development/
18. exp behavior disorder/ or attention deficit disorder/
19. exp parental deprivation/
20. (death\$ or loss\$).mp.
21. exp PARENT/
22. 20 and 21
23. or/6-19
24. 22 or 23

25. (parent\$ or family\$ or mother\$ or father\$ or pregnan\$).mp.

26. exp child development/
27. exp behavior disorder/ or attention deficit disorder/
28. (baby or babies or toddler\$).mp.
30. Infant/
31. child\$.mp.

32. (interven\$ or prevent\$ or program\$ or treatment\$ or effect\$ or therap\$ or outome\$ or result\$).mp.

33. 26 or 27
34. or/28-31
35. 5 or 24
36. 35 and 25 and 33 and 34 and 32

PsycInfo

1. exp At Risk Populations/
2. exp Risk Factors/
3. exp Risk Assessment/
4. (risk\$ or vulnerable\$).mp.
5. or/1-4

6. exp Mental Disorders/
7. exp Drug Addiction/
8. exp Drug Abuse/
9. exp minority groups/
10. exp Adolescent Pregnancy/
11. exp Attachment Disorders/
12. exp Parent Child Relations/
13. exp Learning Disorders/
14. exp social issues/
15. exp Foster Care/
16. exp childhood development/
17. exp Behavior Disorders/ or exp Behavior Problems/
18. exp PREMATURE BIRTH/
19. exp Psychological Stress/
20. exp Mental Retardation/
21. exp physical disorders/
22. exp Adolescent Mothers/
23. or/6-22

24. (parent\$ or famil\$ or mother\$ or father\$ or pregnan\$).mp. [mp=title, abstract, subject headings, table of contents, key concepts]

25. exp childhood development/
26. exp Behavior Disorders/ or exp Behavior Problems/
27. 25 or 26

28. (baby or babies or toddler\$).mp.
29. child\$.mp.
30. or/28-29

31. (interven\$ or prevent\$ or program\$ or treatment\$ or effect\$ or therap\$ or outcome\$ or result\$).mp.

32. 5 or 23
33. 32 and 24 and 27 and 30 and 31

Cochrane

- #1 MeSH descriptor Vulnerable Populations explode all trees
- #2 MeSH descriptor Risk Factors explode all trees
- #3 MeSH descriptor Risk Assessment explode all trees
- #4 (risk* or vulnerable*)
- #5 (#1 OR #2 OR #3 OR #4)

- #6 MeSH descriptor Social Problems explode all trees
- #7 MeSH descriptor Mental Disorders explode all trees
- #8 MeSH descriptor Substance-Related Disorders explode all trees
- #9 MeSH descriptor Minority Groups explode all trees
- #10 MeSH descriptor Pregnancy in Adolescence explode all trees
- #11 MeSH descriptor Parent-Child Relations explode all trees
- #12 MeSH descriptor Learning Disorders explode all trees
- #13 MeSH descriptor Child of Impaired Parents explode all trees
- #14 MeSH descriptor Stress, Psychological explode all trees
- #15 MeSH descriptor Infant, Premature explode all trees
- #16 MeSH descriptor Premature Birth explode all trees
- #17 MeSH descriptor Infant, Premature, Diseases explode all trees
- #18 MeSH descriptor Mental Retardation explode all trees
- #19 MeSH descriptor Disabled Persons explode all trees
- #20 MeSH descriptor Foster Home Care explode all trees
- #21 MeSH descriptor Child Development explode all trees
- #22 MeSH descriptor Mental Disorders Diagnosed in Childhood explode all trees
- #23 (#6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)

- #24 MeSH descriptor Child Development explode all trees
- #25 MeSH descriptor Mental Disorders Diagnosed in Childhood explode all trees
- #26 #24 OR #25

- #27 parent* or famil* or mother* or father* or pregnan*

- #28 child*
- #29 baby or babies or toddler*
- #30 MeSH descriptor Child, Preschool explode all trees
- #31 MeSH descriptor Infant explode all trees
- #32 (#28 OR #29 OR #30 OR #31)

- #33 (#5 OR #23)
- #34 (#33 AND #26 AND #27 AND #32)

Appendix 2: Checklist for Early Intervention Reviews

Your name and date:

First author of the review and year of publication:

1. **Were the search methods used to find evidence (primary studies) on the primary question(s) stated?**

NO
PARTIALLY
YES

Comments:

2. **Was the search for evidence reasonably comprehensive?**

NO
PARTIALLY
YES

Comments:

What was the date of the last search?

What was the date of publication for the most recent trial included?

3. **Were the criteria used for deciding which studies to include in the review reported?**

NO
PARTIALLY
YES

Comments:

Were studies other than RCTs included?

4. **Was bias in the selection of articles avoided?**

NO
PARTIALLY
YES

Comments:

5. Were the criteria used for assessing the validity of the studies that were reviewed reported?

NO
PARTIALLY
YES

Comments:

6. Was the validity of all of the studies referred to in the text assessed using appropriate criteria (either in selecting studies for inclusion or in analyzing the studies that are cited)?

NO
PARTIALLY
YES

Comments:

Was concealment of allocation assessed & reported for each included trial?

Was blinding assessed and reported for each trial?

Was follow-up assessed and reported?

Any other important criteria worth considering?

7. Were the methods used to combine the findings of the relevant studies (to reach a conclusion) reported?

NO
PARTIALLY
YES

Comments:

8. Were the findings of the relevant studies combined appropriately relative to the primary question the review addresses?

NO
PARTIALLY
YES

Comments:

Was meta-analysis used?

Fixed or random effects?

Any concerns or uncertainty about the analysis?

9. Were the conclusions made by the author(s) supported by the data and/or analysis reported in the review?

NO
PARTIALLY
YES

Comments:

Note any conclusions that are either of concern because they are not supported or are worth capturing because they are insightful.

10. Overall, how would you rate the scientific quality of this review?

Extensive flaws		Major flaws		Minor flaws		Minimal flaws
1	2	3	4	5	6	7

Comments: